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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/788,650

Applicant(s)

KHOSLA ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 1-6 and 8-17 is/are ~~allowed~~ allowable. *See 4/3/06*
6) ☒ Claim(s) 7 and 18-22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed January 18, 2006 is acknowledged. Claims 1-22 remain pending and under examination.
2. The following objection and rejections are withdrawn:
 - The objection to the specification for containing alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c), is withdrawn. Applicant was requested to verify if the alteration on page 63, line 10, was Applicant's. Applicant has confirmed that no such alternation was made.
 - The terminal disclaimer filed on January 18, 2006, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,274,560 has been reviewed and are accepted. The terminal disclaimer has been recorded. Therefore, the rejection of claims 12-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of prior U.S. Patent No. 6,274,560 B1 is withdrawn.
 - The rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Kao *et al.* (*Science*, 1994, 265:509-512, "Kao") in view of Donadio *et al.* (*PNAS USA*, 1993, 90:7119-7123, "Donadio (1993)") and Donadio *et al.* (*Gene*, 1992, 115:97-103, "Donadio (1992)") is withdrawn in view of Applicant's persuasive arguments.
 - Applicant argues that there is no suggestion in the combination of Kao and the two Donadio publications to modify a PKS to achieve the instant invention. Specifically, there is no motivation to prevent the utilization of the PKS native

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starter unit. In response to Applicant's substantive argument, Kao indicates that there is some flexibility on the part of the erythromycin PKS with respect to its ability to incorporate alternative acyl starter units. However, there is no teaching or suggestion to modify the PKS such that its native starter unit is prevented from being utilized.

Obviousness-Type Double Patenting

3. Claims 12 and 19-22 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of prior U.S. Patent No. 6,531,299 B1. Previously, claims 13-18 were also included in this rejection, however, in view of Applicant's persuasive argument, the rejection over claims 13-18 is withdrawn.

With regard to claims 12 and 19-22, Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that there is nothing in the claims of the patent that speaks to the invention presently claimed. The claims in the patent are directed to cell-free synthesis using polyketide synthases in general. Applicant argues that there is nothing at all in the claims about utilizing diketide substrates or destroying the ability of a PKS to utilize its native starter unit.

In response to Applicant's argument, the instantly claimed embodiment in claims 12 and 19-22 encompasses a cell-free system, rendering the patented claims (cell-free system) a species of the instantly claimed genus. A species anticipates a genus. With regard to Applicant's argument that there is nothing at all in the claims about utilizing diketide substrates or destroying the ability of a PKS to utilize its native starter unit, the patented claims require that a substrate (a

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starter unit and at least one extender) be added to the cell-free system. Adding a substrate to the cell-free PKS system implies that the PKS system is not using its own native starter unit. As for the diketide substrate of the instant claims, the patented claims also use a diketide substrate, though not explicitly stated. The diketide of the instant claims is formed by coupling a starter unit (acetyl CoA, for example) with an extender unit. The patented claims couple a starter unit (acetyl CoA, for example) with an extender unit. Therefore, the subject matter of the instant claims (12 and 19-22) and the subject matter of the patented claims is not patentably distinct.

Claim Rejections - 35 USC § 112

4. The rejection of claims 7 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that *S. coelicolor* strain CH999 is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of *S. coelicolor* strain CH999. See 37 CFR 1.802. One cannot practice the claimed invention without the strain. Therefore, access to *S. coelicolor* strain CH999 is required to practice the invention. The specification does not

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provide a repeatable method for the exact *S. coelicolor* strain CH999 without access to *S. coelicolor* strain CH999 and it does not appear to be readily available material.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that *S. coelicolor* strain CH999 is readily available to the public, evidenced by Kao et al. (*Science*, 1994, 265:509-512) and McDaniel et al. (*Science*, 1993, 262:1546). Applicant argues that materials published in *Science* must be accessible to the public, thus demonstrating that the strain is available.

In response to this argument, the Office acknowledges that the strain is known, however, Applicant's arguments are not found convincing essentially for the reasons of record. In conjunction with MPEP 2404.02-2400-6, Applicant asserts that materials published in *Science* must be made available to the public, *S. coelicolor* strain CH999. However, biological materials must be known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. The fact that Applicant and other members of the public were able to obtain the material in question from the authors of the *Science* article(s) prior to and after the filing date of the application does not establish the upon issuance of a patent on the application that such material would continue to be accessible to the public. Applicant has not made of record any of the facts and circumstances surrounding the access to the biological material from the authors, nor is there any evidence as to the authors' policy regarding the material if a patent would be granted. Further, there is no assurance that the authors would allow unlimited access to the material if the application has matured into a patent. In the absence of evidence that the *S. coelicolor* strain CH999 is readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed

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upon the granting of a patent, Applicant's arguments are not persuasive and the rejection is maintained.

Deposit of *S. coelicolor* strain CH999 in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strain would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen 4/3/06

Stacy B. Chen
Primary Examiner
April 3, 2006